onal Application No PCT/DK2004/000573

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/436 A61K9/16

A61K9/14

A61P37/06

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, EMBASE, MEDLINE, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT								
Category °	Citation of document, with indication, where appropriate, of the	relevant passages	Relevant to dalm No.					
X	WO 01/37808 A (LIPOCINE INC) 31 May 2001 (2001-05-31)	1-10, 12-16, 21,25, 29,30, 35-40, 42, 47-51,53						
	example 20; claim 1, 5							
X	EP 1 064 942 A (FUJISAWA PHARM/CO) 3 January 2001 (2001-01-03)							
X Fui	ther documents are listed in the continuation of box C.	-/  Patent family members are listed	n annex.					
Special of the cons  A' docum cons  E' earlier filling  L' docum which chart  O' docum other  P' docum  P' docum	nent defining the general state of the art which is not idered to be of particular relevance of document but published on or after the international date ent which may throw doubts on priority claim(s) or his cited to establish the publication date of another on or other special reason (as specified) nent referring to an oral disclosure, use, exhibition or means ent published prior to the international filing date but than the priority date claimed	<ul> <li>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>*&amp;* document member of the same patent family</li> </ul>						
Date of the	e actual completion of the international search	Date of mailing of the international sea	rch report					
	8 November 2004	· 30/11/2004						
Name and	I mailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2  NL - 2280 HV Rijswijk  Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  Fax: (+31-70) 340-3016	Authorized officer  Borst, M						

Inte anal Application No
PCT/DK2004/000573

	PC1/DR2004/0005/3
	Relevant to claim No.
Citation of document, with indication, where appropriate, of the relevant passages	TIGOVALIA TO GLALIA VIO.
SANO N ET AL: "Oral FK 506 blood levels are elevated in pig short bowel model: Further investigations with co-administration of an intestinal CYP3A4 inhibitor."  TRANSPLANTATION PROCEEDINGS, vol. 34, no. 3, May 2002 (2002-05), pages 1050-1051, XP002304068 ISSN: 0041-1345 page 1051, paragraph entitled "Discussion"	1-53
WO 03/004001 A (HOLM JANNIE EGESKOV; MOELLGAARD BIRGITTE (DK); BUUR ANDERS (DK); HOLM) 16 January 2003 (2003-01-16) cited in the application claims 1-56	1-53
HONBO T ET AL: "The oral dosage form of FK-506" TRANSPLANTATION PROCEEDINGS 1987 UNITED STATES, vol. 19, no. 5 SUPPL. 6, 1987, pages 17-22, XP0009024313 ISSN: 0041-1345 table 2; figure 4, 6	1-53
NISHI K ET AL: "The expression of intestinal CYP3A4 in the piglet model." TRANSPLANTATION PROCEEDINGS, vol. 36, no. 2, March 2004 (2004-03), pages 361-363, XP002304069 ISSN: 0041-1345 page 363, paragraph entitled "Discussion"	1-53
NISHI K ET AL: "The colon displays an absorptive capacity of tacrolimus." TRANSPLANTATION PROCEEDINGS, vol. 36, no. 2, March 2004 (2004-03), pages 364-366, XP002304070 ISSN: 0041-1345 page 365-366, paragraph entitled "Discussion"	1-53
	are elevated in pig short bowel model: Further investigations with co-administration of an intestinal CYP3A4 inhibitor." TRANSPLANTATION PROCEEDINGS, vol. 34, no. 3, May 2002 (2002-05), pages 1050-1051, XP002304068 ISSN: 0041-1345 page 1051, paragraph entitled "Discussion" ———— WO 03/004001 A (HOLM JANNIE EGESKOV; MOELLGAARD BIRGITTE (DK); BUUR ANDERS (DK); HOLM) 16 January 2003 (2003-01-16) cited in the application claims 1-56  HONBO T ET AL: "The oral dosage form of FK-506" TRANSPLANTATION PROCEEDINGS 1987 UNITED STATES, vol. 19, no. 5 SUPPL. 6, 1987, pages 17-22, XP0009024313 ISSN: 0041-1345 table 2; figure 4, 6  NISHI K ET AL: "The expression of intestinal CYP3A4 in the piglet model." TRANSPLANTATION PROCEEDINGS, vol. 36, no. 2, March 2004 (2004-03), pages 361-363, XP002304069 ISSN: 0041-1345 page 363, paragraph entitled "Discussion" ——— NISHI K ET AL: "The colon displays an absorptive capacity of tacrolimus." TRANSPLANTATION PROCEEDINGS, vol. 36, no. 2, March 2004 (2004-03), pages 364-366, XP002304070 ISSN: 0041-1345 page 365-366, paragraph entitled



Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)
This international Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy:Although claim 47 involves a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.  2. Claims Nos.:
Claims Nos.:     because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
1. As all required additional search fees were timely paid by the applicant, this international Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest
No protest accompanied the payment of additional search fees.

Information on patent family members

Int: nal Application No PCT/DK2004/000573

Patent document dited in search report		Publication date		Patent family member(s)		Publication date
WO 0137808	Α	31-05-2001	US	6248363	B1	19-06-2001
010.000	. •		AU	1798101		04-06-2001
			CA	2391923		31-05-2001
			EP	1233756		28-08-2002
			ĴΡ		T	27-05-2003
			WO	0137808		31-05-2001
			ÜS	2003077297		24-04-2003
			US	2003180352		25-09-2003
			US	2003215496		20-11-2003
			US	2003064097		03-04-2003
EP 1064942	Α	03-01-2001	AT	269075		15-07-2004
			AU	749623		27-06-2002
			AU	2856399		18-10-1999
			BR	9909201		14-11-2000
			CA	2322516		07-10-1999
			DE	69918074		22-07-2004
			DE	69918074		04-11-2004
			EP	1064942		03-01-2001
			HR	20000707		31-12-2001
			HU	0101237		28-09-2001
			NO		A	23-11-2000
			NZ	507211		25-07-2003
			RU	2214244		20-10-2003
			SK	14392000		12-03-2001
			US	6440458		27-08-2002
			CN	1301157	T	27-06-2001
			EP	1421939		26-05-2004
		•	ID	27825		26-04-2001
			WO	9949863		07-10-1999
			PL	343096		30-07-2001
			TR	200002771		21-02-2001
			TW	570814		11-01-2004
			US	2003235614		25-12-2003
			US	2002044967		18-04-2002
			ZA	200004963	Α	08-01-2002
WO 03004001	Α	16-01-2003	BR	0210867	Α	29-06-2004
			CA	2452330		16-01-2003
			WO	03004001		16-01-2003